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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,669	04/30/2001	Philippe Marliere	205907USOPCT	9510

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

18

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,669

Applicant(s)

MARLIERE ET AL.

Examiner

Gerald G Leffers Jr., PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 7/28/03 as Paper No. 17, wherein the pending claims were cancelled (claims 1-51) and new claims were added (claims 52-85). Claims 52-85 are pending and under consideration in the instant application.

Any rejection of record in the previous office action not addressed herein is withdrawn. This action is not final due to additional grounds of rejection made herein that could have been made in the previous action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-72, 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

The rejected claims are drawn to host cells obtained by methods of selection wherein a missense mutation is incorporated into a an essential gene required for growth of the host cell and the cell is grown under selective conditions wherein 1) the culture medium does not contain a nutrient that will compensate for the lack of a functional copy of the essential gene product, and 2) the culture medium contains an amino acid not encoded by the missense mutation and

Art Unit: 1636

which will restore function to the mutated protein when incorporated into the mutated protein.

There is no explicit limitation that the mutation present in the tRNA synthetase is necessarily the same mutation allowing growth of the host cell. The claims encompass any mutant of any gene that will compensate for the loss of the essential gene product. For example, loss of an essential drug resistance marker might be compensated for by the generation of a “leaky” mutant of a protein pump on the cell surface. Thus, the rejected claims encompass a number of different mutants that do not necessarily include mutants of a tRNA-synthase gene corresponding to the missense codon and which would differ depending upon the nature of the essential gene. The instant specification, and prior art, appear to only describe embodiments wherein a mutant tRNA synthase gene is identified that can incorporate an amino acid and do not provide a basis to envision what particular mutations might occur that compensate for the loss of a given essential protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-85 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is vague and indefinite in that the metes and bounds of the phrase “an amino not encoded” are unclear. It appears that it would be remedial to amend the claim language to read “an amino acid not encoded”.

Art Unit: 1636

Claim 53 is vague and indefinite in that it doesn't specify exactly what is cultured in the second culture media and at what stage the second culturing step is to occur (e.g. prior to the first incubation/selection step or after selection is complete).

Claim 61 is vague and indefinite in that it is unclear whether the claim is meant to specify that a homologous recombination event between the vector comprising a sequence of the gene encoding the essential protein comprising the missense mutation and a native target sequence, or whether it simply means a vector comprising the entire mutated sequence is introduced into the host cell.

The metes and bounds of claim 63 are unclear in that the cells that grow in the culturing step of claim 52 would necessarily be selected for growth.

Claim 68 is vague and indefinite in that the metes and bounds of the phrase "technique of genetic recombination" are unclear. Does the term encompass the natural techniques in which mutations in genes arise in nature, or does it simply mean that the mutated tRNA synthetase gene was generated *in vivo* spontaneously?

Claim 70 is vague and indefinite in that the metes and bounds of the term "generic" recombination technique are unclear. The term does not appear to be clearly defined in the instant specification and is inherently indefinite. What would constitute a "non-generic" technique, for example?

Claim 75 is vague and indefinite in that there is no clear and positive prior antecedent basis for the words "the cell pellet obtained from (b)".

Claim 85 is vague and indefinite in that the metes and bounds of the phrase "functionalizing the isolated protein" are unclear.

Art Unit: 1636

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


GERRY LEFFERS
PRIMARY EXAMINER

Gerald G Leffers Jr., PhD
Examiner
Art Unit 1636

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